University at Buffalo
Research and Economic Development

The Use of Controlled Substances in Research Policy

Who this Policy Applies To

This policy applies to all researchers (faculty, staff, or student) who will a) be a registrant for a controlled substance license, or b) have access to controlled substances.

Policy Statement

Certain research activities conducted under the auspices of the University require the use of controlled substances. Controlled substances, which are substances with high potential for abuse, are identified in the schedules contained within the "Controlled Substances Inventory List," published by the U.S. Drug Enforcement Administration (DEA). In conducting research with controlled substances, University authorized employees must comply with federal and state laws and regulations regarding their use, including DEA registration and New York State Department of Health licensure; storage requirements; inventory maintenance; substance disposal; and reporting and record keeping, in accordance with Title 21, Part 1300-1308 of the Code of Federal Regulations (CFR) and Article 33 of the New York State Public Health Law.

Responsible Party

Authorized University or Research Foundation employees, including principal investigators or supervisors of research in which controlled substances are used, bear full responsibility for complying with Federal and state laws and regulations, and with University policy regarding their use. Specifically, they are responsible for:

- Obtaining and maintaining appropriate licensure from the New York State Department of Health.
- Obtaining and maintaining appropriate registration from the DEA.
- Establishing security measures for the purchase, acceptance, use, and ultimate disposal of the controlled substances used in their research.
- Providing the UB Office of Research Compliance with copies of the appropriate New York State License and DEA registration.
- Providing the UB Office of Research Compliance with the names and emails of individuals who will have access to the controlled substances.

When applicable, investigators or supervisors of research in which controlled substances will be used are responsible for obtaining approval for their use from the appropriate University committees that oversee human subject and animal subjects research (e.g., the relevant Institutional Review Board or the Institutional Animal Care and Use Committee) and must report their intention to use controlled substances to external funding sponsors upon submission of grant applications. Individuals who have obtained the appropriate state and federal registration to use controlled substances and who have notified the UB Office of Research Compliance of same are authorized to purchase, accept, and dispose of these substances.

Oversight

The Office of Research Compliance will assist investigators in complying with applicable rules and regulations, and provide information regarding regulatory requirements.

Purchasing Controlled Substances

Orders for controlled substances by DEA registrants (i.e., authorized University or Research Foundation employees) must be submitted to the appropriate University Purchasing Department on a requisition signed by the registrant or authorized designee. DEA Form 222 and a copy of the DEA registration must accompany the requisition.

Receiving Controlled Substances

The controlled substances must be shipped to the registrant and address as indicated on the DEA registration. Once received, the controlled substances should be opened to verify the contents and any discrepancies should be rectified with the supplier. If discrepancies cannot be rectified, the Office of Research Compliance and the DEA should be contacted by the registrant. From the time a controlled substance is accepted on campus until it is consumed or disposed of, a record (disposition record) of the chain of custody must be kept at each point where the substance changes hands or is used. The record is completed at each point by the person delivering the substance and includes the name of the substance, the quantity, and the signature of the person receiving it. The person making the withdrawal shall sign all records of withdrawals of controlled substances from storage.

Continuing Records

The registrant shall maintain an accurate continuing record or log of each controlled substance received, disposed of, or otherwise used by him or her, in accordance with 21 CFR 1304.21 and 1304.24. The registrant for each registered location and for each independent activity for which the registrant is registered shall maintain separate records. The registrant must maintain the continuing records for 5 years.

The records shall include the following information:

1. Chemical or botanical name of each substance kept at the site.
2. Identification of each substance and the number of units or total volume in each commercial container.
3. The number of commercial containers received; the date of and number of containers in each receipt; and the name, address, and registration number of the source from which the containers were received.
4. The amount of each substance transferred or used, including the name and address of the person(s) to whom it was given, the date of transfer, the name of the individual who used the substance, and the reason it was used.
5. The number of units or volume and/or commercial containers disposed of in any other manner, as well as the date and manner of the disposal.

Inventory

Each DEA registrant must maintain an accurate inventory of controlled substances. The registrant will conduct a biennial inventory and reconciliation as part of a self-audit. Inventories for schedule I and II controlled substances shall be maintained separately from other laboratory records. A copy

of the completed inventory must be retained for 5 years and be made available to the University or regulatory authorities when requested.

The inventory will include the following information:

1. Chemical or botanical name of substance.
2. Number of units or total volume of each substance in each commercial container.
3. Number of commercial containers of each substance.

For guidance regarding damaged, defective, or impure substance awaiting disposal, see 21CFR 1304.15(d).

Any discrepancy in the continuing record or inventory of controlled substances must be reported to the University Police and the Office of Research Compliance immediately upon discovery.

Storage

All DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. The following are considered in determining security requirements: the type of activity, the type and form of controlled substance, the quantity of controlled substance, the location of the premises, the type of building construction, the type of vault, safe, and secure enclosures, the adequacy of key control systems, the adequacy of electric detection and alarm systems, the extent of unsupervised public access, the adequacy of supervision over employees with access, procedures for handling visitors, the availability of local police and adequacy of the use and disposal tracking system (CFR 1301.71-1301.76).

Disposal

The registrant having custody of the controlled substance shall dispose in accordance with University policy and federal regulations. Any questions or difficulties regarding the disposal of controlled substances should be directed to Environmental Health and Safety.

Termination of Registrant Employment

Prior to departure from the University, the registrant must notify the Office of Research Compliance of their intent to leave, and work with the office to modify, transfer, or terminate any registrations according to (21 CFR 1301.52). Custody of any controlled substances by registrant must be transferred or substances disposed of as outlined above.

Non-Registrant Personnel

21 CFR 1301.76 states that, “registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause.” This requires that any researcher (faculty, staff, or student) who has access to controlled substances must complete a DEA screening certification and undergo a background check. The registrant must work with the Office of Research Compliance and University Human Resources to satisfy these requirements using the form attached to this policy.

Relevant Federal and State Regulations Concerning Controlled Substances

Federal: Title 21 CFR Part 1300

State: NY Department of Health, Statutory Authority: Public Health Law, Sec. 225, NYCRR Title 10, Part 80 - Rules and Regulations on Controlled Substances

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Policy History

Date	**Changes**
2008	Original Policy
2024	• Changed contact Research Compliance **Officer** to **Office of Research Compliance** • Changed three years to five years for inventory records (per regulations) • Added Section on Termination of registrant • Added section on Non-Registrant Personnel • Changed registrant annual inventory review to biennial inventory review • Added hyperlinks • Updated inquiry contacts • Added Form

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Controlled Substance Access
Background Check Consent and Request Form

I am an individual who will have access to controlled substances. I understand that the University at Buffalo is required to perform a background check, including a criminal history check to allow access.

I consent to this check to be conducted upon submission of this form.

Date:_____

Legal Name:_____

UB Email Address:_____

Phone Number:_____

Name of License Holder: _____

SEND COMPLETED FORM TO: ub-irb@buffalo.edu with the Subject line: Controlled Substances Background Check

UB Office of Research Compliance
Office of the Vice President for Research and Economic Development